



NEWS RELEASE

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Health Agencies Awarded Grant to Help Prevent Accutane (isotretinoin)-Related Birth Defects

(Salt Lake City, UT) – The University of Utah Health Sciences Center in collaboration with the Utah Department of Health (UDOH), and the Organization of Teratology Information Services (OTIS), has received a grant to find out why women who take Accutane (isotretinoin), a drug to treat severe acne, continue to get pregnant despite warnings that the drug causes serious birth defects if taken during pregnancy.

The one-year \$83,000 grant, funded by the Centers for Disease Control and Prevention's National Center on Birth Defects and Developmental Disabilities and Office of Women's Health, was awarded to the Pregnancy RiskLine (PRL), a counseling service of the UDOH and University of Utah Health Sciences Center.

"Our goal is to reduce the number of pregnancies exposed to Accutane (isotretinoin)," says the study's principal investigator, John C. Carey, M.D., M.P.H., Professor of Pediatrics and PRL Medical Director. Before prescribing Accutane (isotretinoin) doctors must make sure women are using two forms of birth control and understand the birth defects risks. "Despite these efforts an increasing number of women continue to get pregnant while using Accutane (isotretinoin)," added Carey.

The project will survey women throughout North America who took Accutane (isotretinoin) during pregnancy. The Pregnancy RiskLine and other experienced centers will provide birth defects counseling to the pregnant woman with exposure to Accutane (isotretinoin). The programs will also gather information about the amount of Accutane (isotretinoin) used, how the product was dispensed, birth control methods used and how women perceived the manufacturer's new pregnancy prevention program called S.M.A.R.T. (System to Manage Accutane Related Teratogenicity). Roche Laboratories voluntarily created the program for women who use Accutane (isotretinoin).

“Data from this project will help us know whether the S.M.A.R.T. program works,” says Lynn Martinez, project director and program manager of UDOH’s Pregnancy RiskLine. “Information from the survey will help us understand which pregnancy prevention strategies work best. We can then share this information with health care providers, pharmaceutical companies and the public.”

More than 2 million people use Accutane (isotretinoin) for cystic acne in the U.S. each year. Accutane (isotretinoin) is a known teratogen – which means the drug causes birth defects in fetuses of women who take it during pregnancy. Defects of the brain, face, ears, heart and thymus are seen 25 to 35 percent of the time. A child born with these birth defects may be at an increased risk for infant death.

Children may also have a variety of developmental problems – including hearing, vision, motor and mental deficits – even when structural defects are not present at birth. These problems range from severe deafness and blindness to subtle vision problems that can be corrected by prescription glasses. Some children exposed to Accutane (isotretinoin) are mentally retarded, while others have problems with attention span, hand-eye coordination, and organizational abilities. Many of these difficulties are not noticed at birth, but discovered later in childhood. The long-term effects on any exposed child are still unknown. With Accutane (isotretinoin) exposure in pregnancy, the risk for miscarriage may be as high as 40 percent, or 3 to 4 times greater than the usual rate of pregnancy loss.

“The risk of serious birth defects with Accutane use is high, and many pregnancies are unplanned,” commented Dr. José Cordero, director of the CDC's National Center on Birth Defects and Developmental Disabilities. “We support the development of effective programs that can inform women about the risks, and assist them in avoiding pregnancy while using this medication.”

To receive counseling on the birth defects caused by Accutane (isotretinoin) or if you have questions about medications, chemicals or infections during pregnancy or while breastfeeding, call the PRL at 328-2229 (Salt Lake area) or 1-800-822-2229 (outside of Salt Lake).